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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Ann Marie Schmidt and David Stern	
Serial No.	:	09/166,649	Examiner: E. O'Hara
Filing Date	:	October 5, 1998	Art Unit: 1646
For	:	METHODS FOR DETERMINING WHETHER A COMPOUND IS CAPABLE OF INHIBITING THE INTERACTION OF A PEPTIDE WITH RAGE	

1185 Avenue of the Americas
New York, New York 10036
September 10, 1999

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

COMMUNICATION IN REPLY TO JUNE 10, 1999 OFFICE ACTION AND PETITION FOR A TWO-MONTH EXTENSION OF TIME

This Communication is submitted in reply to the June 10, 1999 Office Action issued by the U.S. Patent and Trademark Office in connection with the above-identified application. A response to the June 10, 1999 was originally due July 10, 1999. Applicants hereby request a two-month extension of time from July 10, 1999 to September 10, 1999. The fee for a two-month extension of time for a small entity is ONE HUNDRED AND NINETY DOLLARS ($190.00) and a check including this amount is enclosed herewith. Applicants have previously established small entity status. Thus, a reply is now due September 10, 1999. Accordingly, this Communication is being timely filed.

The Examiner stated claims 1-57 are pending in the instant application.

Restriction/Election

The Examiner required restriction to one of the following allegedly independent and distinct inventions under 35 U.S.C. §121:

I. Claims 1-13 and 15-29, drawn to a method for determining whether a compound is capable of inhibiting the interaction of a peptide with a receptor for advanced glycation end product;

II. Claims 14 and 53-57, drawn to a compound;

III. Claims 30 and 31, drawn to a method of assaying whether a compound can inhibit a peptide-receptor interaction in a transgenic animal; and

IV. Claims 32-52, drawn to a method of inhibiting the interaction of an advanced glycation end product with a receptor for advanced glycation end product in a subject, comprising administering to the subject an inhibitory compound.

The Examiner stated that alleged invention II and each of alleged inventions I, III and IV are related as product and process of use. The Examiner stated that the product that is alleged invention II can be used in the invention of group I to inhibit a peptide-receptor interaction in vitro, or in the invention of group II by using a transgenic animal, or it can be used as a therapeutic agent as in the invention of group IV.

The Examiner further stated alleged inventions I, III and IV are unrelated. The Examiner stated that each of the alleged inventions require different starting materials and have different steps, methods and goals. The Examiner stated that because these inventions are distinct for the reasons given above and the search required for each of the groups is not required for others, restriction for examination purposes as indicated is proper.

In reply, without conceding the correctness of the Examiner's position, **applicants elect with traverse group I, claims 1-13 and 15-29 for examination on the merits.** Applicants traverse the restriction requirement and request that the Examiner consider joining groups I, II, III and IV for examination together in the interest of compact prosecution.

Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required when two or more independent and distinct inventions are claimed in one application. Under MPEP §803, the Examiner must examine the application on the merits, even though it claims distinct inventions, if search and examination can be made without serious burden.

Applicants maintain that it would not be a burden for the Examiner to search groups I-IV together since such groups do not define distinct inventions. 35 U.S.C. § 121 states "[i]f two or more independent *and* distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions" (emphasis added). In defining the term "related," the M.P.E.P. states, "the term 'related' is used as an alternative for 'dependent' in referring to subjects other than independent subjects." M.P.E.P. § 802.01.

Further, applicants respectfully point out that under M.P.E.P. § 803, the Examiner must examine the application on the merits, even if it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely: (1) the invention must be independent and distinct; and (2) there must be a serious burden on the Examiner if restriction is

not required. Applicants contend that there would not be a serious burden on the Examiner if restriction is not required between the groups as listed above. This is so because a search of the prior art for subject matter defined by claims in any one of Groups I-X would necessarily overlap and possibly identify art pertaining to the subject matter defined by claims in any of the other Groups (e.g. all involve compounds which inhibit the interaction between a peptide with a receptor for advanced glycation endproduct). Therefore, it would not be a serious burden for the Examiner to examine the groups joined as set forth above. Accordingly, in view of the foregoing remarks, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement.

Election of Species

The Examiner stated that claims 1-13, 15-31 and 49-52 are generic to a plurality of distinct species of:

a) **peptide:** carboxymethyl-modified, carboxymethyl-lysine-modified, and synthetic, as in claims 3, 4 and 5,

b) **derivatization of the peptide:** aryl, alkyl, acetyl, propyl, isopropyl, butyl, isobutyl, and carboxymethyl, as in claims 9-12,

c) **compound:** net negative charge, net positive charge, SRAGE, peptidomimemtic, organic molecule, polypeptide, nucleic acid, inorganic molecule, less than 10,000 daltons, antibody, humanized, chimeric, primatized, mutated AGE and mutated RAGE, quinine, derivative of quinine, quinidine and derivative of quinidine as in claims 14-23 and 49-52.

The Examiner noted claims 37-43 and 53-56 are generic to a plurality of distinct species of **disease states:** diabetes, systemic lupus erythematosus, inflammatory lupus nephritis, amyloidoses, inflammation, obesity, advanced age and kidney failure.

The Examiner noted claim 33 is generic to a plurality of **subjects:** human, primate, mouse, rat and dog.

The Examiner further noted Claim 32 is generic to a plurality of modes of administration: intralesional, intraperitoneal, intramuscular injection, intravenous injection, infusion, liposome-mediated delivery topical, nasal, oral, ocular and otic delivery.

The Examiner stated claims 45-48 are generic to a plurality of **carriers:** diluent, virus, liposome, microencapsule, polymer encapsulated cell, retroviral vector, time release implant, aerosol, intravenous, oral and topical carrier.

The Examiner stated the Examiner stated applicant is required under 35 U.S.C. §121 to elect a single species from each of these seven groups of species of the invention that is elected for further examination on the merits:

1) Peptide

2) derivitization of the peptide

3) compound

4) disease state

5) subjects

6) modes of administration

&) carriers,

even though, this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that are elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The Examiner further stated should applicants traverse on the ground that the species are not patently distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence of admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Examiner noted upon allowance f a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species MPEP §809.2 (a).

The Examiner advised applicants that the reply to this requirement to be complete must include an election of the inventions to be examined and election of each of the species even though the

requirement be traversed.

In reply, applicants elect with traverse species C, a compound.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the $190.00 two-month extension of time fee, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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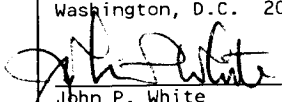

9/10/99
John P. White Date
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